UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEBORAH FELLNER **Plaintiff,** **v.** **TRI-UNION SEAFOODS, L.L.C., d/b/a CHICKEN OF THE SEA,** **Defendant.**	**CASE NO.: 06-CV-688 (DMC)**

PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE ANY MENTION OF THE FDA

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PRELIMINARY STATEMENT

Defendant Tri-Union continually cites FDA authorities in an attempt to show that the FDA approved Defendant's product and labeling at issue. However, FDA authorities are merely guidelines, and are wholly irrelevant to the facts of this case. Accordingly, we ask the Court to grant this Motion *in limine* to bar any mention of the FDA as it relates to Defendant's product or labeling as this would merely confuse the jury as to the real issue in the case: whether Defendant violated the New Jersey Products Liability Act ("NJPLA").

Specifically, Defendant Tri-Union never submitted anything to the FDA for approval, and the FDA never approved Defendant's product. The FDA took no action whatsoever; such inaction on the part of the FDA means that there can be no presumption of adequacy pertaining to Defendant's product or labeling. Second, the issue at trial is whether Defendant violated the NJPLA. All relevant claims have been filed by Plaintiff Deborah Fellner under the NJPLA; the FDA does not make rules or laws, but instead creates guidelines that companies should, but do not always, follow. Therefore, any mention of the FDA is irrelevant; however if the Court finds them relevant, there is a high probability that doing so will confuse the issues for the jury.

Accordingly, any mention of the FDA should be excluded under Federal Rule of Evidence 403 ("Rule 403").

BACKGROUND

Defendant Tri-Union challenges Plaintiff Deborah Fellner's allegation that her daily consumption of albacore tuna over more than a decade exposed her to toxic levels of mercury, resulting in permanent neurological injury. Plaintiff submitted numerous medical reports that detail the extent of her medical issues from mercury exposure.

Defendant Tri-Union attempts to use FDA notices and guidelines in asserting that its product and labeling standards are adequate. However, Defendant never submitted their product or label to the FDA for approval. Given that all Plaintiff's claims are filed under the NJPLA, FDA guidelines are irrelevant and any mention of them will mislead the jury and should be barred under Rule 403.

GOVERNING LAW

Federal Rule of Evidence 401 ("Rule 401"), which applies the test for relevant evidence, provides that "Evidence is relevant if (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed.

R. Evid. 401. Additionally, Federal Rule of Evidence 402 ("Rule 402") simply states "irrelevant evidence is not admissible." Fed. R. Evid. 402.

Federal Rule of Evidence 403 ("Rule 403") allows for relevant evidence to be excluded in certain circumstances. Fed. R. Evid. 403. Rule 403 states that "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, **confusing the issues, misleading the jury**, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403 (emphasis added).

In *Planned Parenthood v. Verniero*, the New Jersey District Court described the Rule 403 analysis:

> The court must balance the probative value and the need for the evidence against the harm likely to result from its admission when conducting a Rule 403 inquiry. The court is vested with broad discretionary authority to determine the balancing issue presented by Fed. R. Evid. 403.

Planned Parenthood v. Verniero, 22 F. Supp. 2d 331, 338 (D.N.J. 1998).

LEGAL ARGUMENT

First, Defendant Tri-Union has never submitted anything to the FDA for approval. The FDA has never reviewed or approved Defendant's product or labeling in this case. Neither Tri-Union nor the FDA has taken any action on Defendant's labeling, and inaction cannot be viewed as action.

Simply put, no action on the FDA's part means that there can be no presumption of adequacy on the labeling.

Second, the issue at bar is whether Defendant violated the NJPLA, not whether Defendant did or did not comply with FDA guidelines. Plaintiff has filed all her claims under the NJPLA, whereas the FDA merely sets guidelines which companies should, but do not always, follow. The use of any materials pertaining to FDA guidelines are wholly irrelevant and should be barred from discussion at trial due to the tendency to mislead that will result from the mere mention of the FDA. In the alternative, if FDA materials are deemed by the Court to be relevant, we argue that the use of said materials will confuse the issue for the jury, and should still be excluded under Rule 403.

I. Defendant's Product was Never Reviewed or Approved by the FDA and the FDA's Inaction Cannot Create a Presumption of Adequacy on the Labeling

Defendant and their experts, including specifically Bolger and Acheson, should be precluded from attempting to mislead the jury into believing that the FDA's inaction in this case creates a presumption of adequacy with regard to Defendant's product or labeling. Defendant never submitted their product to the FDA, and the FDA never reviewed their product or labeling. The fact that the FDA itself did not affirmatively

disapprove of Tri-Union's labeling cannot possibly lead to the inference that that Tri-Union has actively sought to comply with FDA regulations, or that there was any FDA finding that Tri-Union's product had adequate warnings.

The facts in this case are analogous to those contained in *Knipe v. SmithKline Beecham,* 583 F. Supp. 2d 553. There, the plaintiff's complaint alleged that the Defendant drug maker breached its state law duty to warn of the increased risk of suicide in pediatric patients as a result of taking an antidepressant. *Id.* at 556. At the time the drug was prescribed, the FDA had yet to publicly state its position regarding a link between the pediatric use of the drug, or other similar drugs, and an increased risk of suicide. *Id.* at 579, 584. Moreover, the evidence submitted by the parties suggested a triable issue of fact as to whether the drug maker possessed information, not made available to the FDA, upon which it could have unilaterally added a warning to its labeling, consistent with FDA regulations. *Id.* at 584. Mere speculation as to whether the FDA would or would not have approved such a warning was insufficient to create a direct conflict upon which the court could find preemption. *Id* at 555.

The facts of *Knipe* bear resemblance to those within the case at hand. Here, the FDA has yet to publically affirm or deny whether Defendant Tri-Union labeled their product adequately. The evidence already submitted

clearly demonstrates that Defendant possessed information on mercury toxicity, which, if made available to the FDA, could have served as a basis for a required warning or labeling change. Here, as in *Knipe*, the FDA has not reviewed Defendant's product or its labeling. Furthermore, Defendant has never submitted their product to the FDA for review. The FDA took no action here whatsoever, and, as in *Knipe*, mere speculation over whether the FDA would have approved the labeling cannot in any way create a presumption of adequacy as to said labeling. Because of the complete lack of FDA involvement with regard to Defendant's product and labeling, it would be wholly inappropriate to allow Defendant to assert that such inaction creates a presumption of adequacy. Accordingly, this Court should bar any mention of the FDA as it pertains to the approval of Defendant's product and/or labeling.

II. Plaintiff's Claims Are Under the NJPLA and FDA Guidelines Are Irrelevant

As previously stated, Plaintiff brings all claims under the NJPLA. Accordingly, the guidelines set out by the FDA are wholly irrelevant to the facts of the case, and should be barred in accordance with Rules 402, 403 and 702.

In Plaintiff's Motions to bar Defendant's experts Acheson and Bolger, filed contemporaneously with this Motion, Plaintiff argues that any use of

FDA advisories or standards are wholly irrelevant, and, if introduced, can only serve to confuse the jury. In his expert report, Bolger impermissibly applies FDA standards to the facts in his analysis. The court in *Citizens Fin. Group v. Citizens Nat'l Bank* excluded a portion of the reports of two experts, stating: "[the] report does not analyze the relevant facts in light of the applicable . . . standards. The use and application of this **improper standard** would not only be unhelpful to the jury but may mislead the jury and, therefore, should be excluded." *Citizen Financial Group, Inc. v. Citizens Nat. Bank of Evans City*, No. 01-1524, 2003 WL 24010950, at *14 (W.D. Pa., April 23, 2003).

Here, the relevant facts are similar to those in *Citizen*, because Bolger, just as the experts in *Citizen*, fails to analyze the facts in light of the relevant standard: the NJPLA. Nowhere in Bolger's report is the NJPLA or the standard it applies even so much as mentioned. Such application of the facts to improper and irrelevant FDA standards would only serve to confuse the jury. Rule 702 requires that the evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993). Accordingly, we argue that any mention of FDA approval of Defendant's product or labeling will only result in misleading the jury.

Additionally, the report issued by Defendant expert Acheson makes no reference to the NJPLA. Instead, Acheson attempts to apply FDA guidelines to the facts. His report is irrelevant for the same reason as Bolger's report: both attempt to render opinions based on FDA standards, completely ignoring the fact that Plaintiff has filed her case under the NJPLA. The FDA never reviewed this product, nor did Defendant submit their product to the FDA for examination. To allow Defendant to introduce FDA guidelines at trial and through the testimony of their experts would be wholly irrelevant, since all issues arise out of claims filed under the NJPLA and the FDA had no involvement in Defendant's product labeling. Plaintiff further contends that even if FDA guidelines were not barred from trial, admitting them could only result in leading the jury astray from the real issue in this case – whether Defendant violated the NJPLA for failing to disclose the danger of mercury in its product. The probative value of the FDA advisories is insignificant. Whereas, introducing the notion of FDA approval of Defendant's product and labeling, achieved inadvertently only as a result of both Defendant and FDA's inaction, would create great prejudice against Plaintiff's case. The FDA guidelines and advisories Defendant will likely introduce either as exhibits or through experts, would be irrelevant and could only serve to confuse the issue. Accordingly, this

Court should bar any mention of the FDA as approving Defendant's product or labeling.

III. Any Claim that FDA Standards Supersede the NJPLA are Precluded Under the Doctrine of Res Judicata

In the case at hand, the Third Circuit has already held that the FDA's advisories do not preempt the NJPLA. The Third Circuit reversed and remanded this case, holding that the informal actions taken by the FDA (i.e., issuance of a consumer advisory regarding the risks posed by mercury in fish, and establishing a guideline regarding mercury concentrations) were insufficient to preempt state regulatory action. *See Fellner v. Tri-Union Seafoods, L.L.C.,* 539 F.3d 237 (3d Cir. 2008).

Because the Third Circuit has already rendered a final decision in stating that the FDA's advisories were insufficient to preempt the NJPLA, we assert that under the Doctrine of Res Judicata, Defendants should be precluded from bringing any arguments that: (1) the FDA's inaction should preempt the NJPLA; and (2) the FDA approved Defendant's product and/or labeling.

CONCLUSION

Based on the foregoing, Plaintiff respectfully requests that this Court enter the attached order granting Plaintiff's Motion *in Limine* to prohibit

Defendants from mentioning the FDA as approving Defendant's product or labeling.

Respectfully submitted,

/s/ Ed McElroy
Ed McElroy
EICHEN CRUTCHLOW ZASLOW & McELROY
40 Ethel Road
Edison, NJ 08817
Telephone: (732) 777-0100

CERTIFICATION OF SERVICE UPON COUNSEL

I hereby certify that on August 17, 2015, I caused to be electronically filed the foregoing using the Court's CM/ECF system, which sent a notification of such filing to all counsel of record.

/s/ Barry R. Eichen
Barry R. Eichen
EICHEN CRUTCHLOW ZASLOW & McELROY
40 Ethel Road
Edison, NJ 08817
Telephone: (732) 777-0100
beichen@njadvocates.com

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For good cause shown, it is on this day ORDERED as follows:

Defendant Tri-Union Seafoods, LLC is hereby barred from any mention at trial of the FDA, including but not limited to, the following:

1. That any action or inaction by the FDA should preempt Plaintiff's claims under the New Jersey Products Liability Act; and
2. That the FDA in any way approved and/or consented to Defendant's product and/or its labeling in any way.

Date:_____ _____

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CONCLUSION

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Respectfully submitted,

/s/ Ed McElroy
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CERTIFICATION OF SERVICE UPON COUNSEL

I hereby certify that on August 17, 2015, I caused to be electronically filed the foregoing using the Court's CM/ECF system, which sent a notification of such filing to all counsel of record.

/s/ Barry R. Eichen
Barry R. Eichen
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Telephone: (732) 777-0100
beichen@njadvocates.com

UNITED STATES DISTRICT COURT
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